



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0410; FRL-9990-58]

Certain New Chemicals; Receipt and Status Information for November 2018

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 11/01/2018 to 11/30/2018.

DATES: Comments identified by the specific case number provided in this document must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0410, and the specific case number for the chemical substance related to your comment, by one of the following methods:

• *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 11/01/2018 to 11/30/2018. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including

amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the TSCA, 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an “existing” chemical substance or a “new” chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a “new chemical substance,” while a chemical substance that is listed on the TSCA Inventory is classified as an “existing chemical substance.” (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *<https://www.epa.gov/tsca-inventory>*.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for “test marketing” purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to:

<http://www.epa.gov/oppt/newchems>.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the *Federal Register* certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-

FROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the *Federal Register* after providing notice of such changes to the public and an opportunity to comment (See the *Federal Register* of May 12, 1995 (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices>. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs received by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices received by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (i.e., domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g. P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier versions were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Received from 11/01/2018 to 11/30/2018

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-19-0006	1	11/16/2018	Danisco US, Inc.	(G) Production of a chemical substance	(G) Genetically modified microorganism for the production of a chemical substance
J-19-0007	1	11/16/2018	Danisco US, Inc.	(G) Production of a chemical substance	(G) Genetically modified microorganism for

					the production of a chemical substance
J-19-0008	1	11/16/2018	Danisco US, Inc.	(G) Production of a chemical substance	(G) Genetically modified microorganism for the production of a chemical substance
J-19-0009	3	11/21/2018	CBI	(G) Production of basic nitrogen-containing acid	(G) Microorganism producing basic nitrogen-containing acid
J-19-0010	3	11/21/2018	CBI	(G) Production of basic nitrogen-containing acid	(G) Microorganism producing basic nitrogen-containing acid
P-18-0377	3	11/16/2018	CBI	(G) microelectronic use	(G) N,N-Bis(haloalkylsubstituted)sulfamide,
P-18-0385	2	11/14/2018	Colonial Chemical, Inc	(S) Liquid Laundry	(S) D-Glucopyranose, oligomeric, Bu glycosides, polymers with epichlorohydrin, 2-hydroxy-3-sulfopropyl ethers, sodium salts
P-19-0001	2	11/1/2018	Burgess Pigment Company	(G) Filler for plastic	(G) Aluminum silicate clay treated with siloxane (vinyl functionality)
P-19-0012	4	11/8/2018	CBI	(S) Resin component for the polyisocyanurate (S) Resin component in specialty polyurethane kits and systems for aerospace and military applications	(G) Benzenedicarboxylic acid, polymer with isobenzofurandione and oxybis [ethanol]
P-19-0012	5	11/26/2018	CBI	(S) Resin component for the polyisocyanurate (S) Resin component in specialty	(G) Benzenedicarboxylic acid, polymer with isobenzofurandione and oxybis [ethanol]

				polyurethane kits and systems for aerospace and military applications	
P-19-0013	2	11/15/2018	CBI	(S) Surfactant for use in asphalt emulsions	(G) Alkyl Cyclic Amide
P-19-0014	2	11/5/2018	CBI	(S) Emulsifier for use in asphalt applications	(G) Alkyl Cyclic Amide Chloride
P-19-0015	2	11/15/2018	CBI	(S) Emulsifier for use in asphalt applications	(G) Alkyl Cyclic Amide
P-19-0016	2	11/15/2018	CBI	(S) Emulsifier for use in asphalt applications	(G) Alkyl Cyclic Amide Chloride
P-19-0017	2	11/15/2018	CBI	(S) Emulsifier for use in asphalt applications	(G) Alkyl Amide Alcohol
P-19-0018	2	11/15/2018	CBI	(S) Emulsifier for use in asphalt applications	(G) Alkyl Amide Alcohol Chloride
P-19-0019	1	11/8/2018	CBI	(G) Intermediate	(G) Haloalkane
P-19-0020	1	11/8/2018	CBI	(G) Lubricating oil additive	(G) Alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs.,
P-19-0021	1	11/9/2018	Nippon Kayaku America, Inc.	(G) Pigment ink	(G) Hydroxyalkyl carboxylic acid, polymer with alkylamine, alkylene carbonate, alkanediol, isocyanate, compd. with alkylamine
P-19-0022	1	11/9/2018	Nippon Kayaku America, Inc.	(G) Pigment ink	(G) Hydroxyalkyl carboxylic acid, polymer with alkylamine, alkyl carbonate, alkanediol, isocyanate, compd. with alkylamine

P-19-0023	1	11/16/2018	Allnex USA, Inc.	(S) Powder coating resin for industrial application	(G) Substituted carbomonocycle, polymer with substituted carbomonocycles, dialkyl-alkanediol, alkyl-hydroxyalkyl-alkanediol and alkanedioic acid
P-19-0024	1	11/16/2018	Sales and Distribution Services, Inc.	(S) Hot Mix Asphalt Application, (S) Waterproofing Application, (S) Asphalt Emulsion Application	(S) 1-Octadecanaminium, N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride (1:1), reaction products with water, Trimethoxy(propyl) silane, Trimethoxy(methyl) silane, Tetraethyl orthosilicate and ethane-1,2-diol
P-19-0025	1	11/19/2018	Bercen, Inc.	(G) Hydrophobe formulation	(S) 11-Docosene
P-19-0026	1	11/27/2018	Allnex USA, Inc.	(S) The PMN substance is an isolated intermediate incorporated as a component in several allnex coating resin products used as additives for corrosion protection	(G) Alkanoic acid, compds. with substituted carbomonocycle-dialkyl-alkanediamine-halosubstituted heteromonocycle-polyalkylene glycol polymer-dialkanolamine reaction products
P-19-0027	1	11/28/2018	Allnex USA, Inc.	(S) The PMN substance is a component in several allnex coating resin products used as additives for corrosion protection	(G) Substituted Carbomonocycle, polymer with haloalkyl substituted heteromonocycle, dialkyl-alkanediamine and hydro-hydroxypoly[oxy(alkyl-alkanediyl)],

					reaction products with metal oxide and dialkanolamine, acetates (salts)
P-19-0028	3	11/30/2018	CBI	(G) Lubricating oil additive	(G) Alkyl salicylate, metal salts
P-19-0029	1	11/29/2018	Cytec Industries, Inc.	(G) Catalyst	(S) Phosphonium, tributylethyl-, diethyl phosphate (1:1)

In Table II. of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs received by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table II. – NOCs Received From 11/01/2018 to 11/30/2018

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-08-0175	11/06/2018	05/17/2008		(S) Hexanedioic acid, polymer with 1,4-butanediol, dimethyl carbonate, 1,2-ethanediol, 1,6-hexanediol and 1,1'-methylenbis[4-isocyanatobenzene]*
P-11-0069	11/06/2018	06/06/2011		(G) Dispersible isocyanate crosslinker
P-13-0231	11/08/2018	10/16/2018		(G) Alkylmethacrylate polymer, with alkyl acrylate, aromatic vinyl monomer and alkyl acrylate
P-14-0510	11/26/2018	05/15/2015		(S) Amides, vegetable-oil, n,n-bis(hydroxyethyl), reaction products with maleic anhydride and sodium sulfite (2:1)
P-16-0462A	11/02/2018	07/26/2018	To submit a revised generic	(G) Ash (residues), reaction products with

			name	tetraethoxydioxa- polyheteroatom-disilaalkane
P-16-0484	11/06/2018	10/17/2018		(G) Phosphoric acid, metal salt, compd. w/ substituted aromatic heterocycle
P-17-0215	11/21/2018	11/19/2018		(S) 2-butenedioic acid (2z)-, 1,4-dibutyl ester, polymer with 1-hexadecene and 1-tetradecene
P-17-0270	11/14/2018	10/19/2018		(G) Alkyl perfluorinated acryloyl ester
P-17-0278	11/06/2018	10/25/2018		(G) Fatty acid derived imidazoline salts
P-18-0070	11/08/2018	11/05/2018		(G) Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids
P-18-0102	11/09/2018	11/08/2018		(G) Alkenoic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanedio], polymer with alkylcarbonate, alkanediols, substituted alkenoic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt
P-18-0134	11/09/2018	11/07/2018		(S) Benzene, 1-(chloromethyl)-3-methyl-
P-18-0231	11/11/2018	11/09/2018		(G) Alkenoic acid, substituted alkyl-, polymer with isocyanatoalkane, alkyl carbonate, alkanediol and polyalkylene glycol ether with alkyl(substituted alkyl) alkanediol alkenoate, glycerol monoacrylate alkenoate-blocked

In Table III. of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information received by EPA during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 11/01/2018 to 11/30/2018

Case No.	Received Date	Type of Test Information	Chemical Substance
P-18-0293	11/01/2018	<i>In vitro</i> mammalian chromosome aberration test (OECD 473)	(S) propanedioic acid, 2-methylene-, 1,3-dihexyl ester
P-18-0294	11/01/2018	<i>In vitro</i> mammalian chromosome aberration test (OECD 473)	(S) propanedioic acid, 2-methylene-, 1,3-dicyclohexyl ester
P-11-0483	11/02/2018	Avian reproduction test (OECD 206)	(G) alkyl thiol
P-18-0128	11/02/2018	Acute dermal irritation test (OECD 404), Acute eye irritation test (OECD 405), Inherent biodegradation test (OECD 302C)	(S) inulin, 2-hydroxy-3-(trimethylammonio)propyl ether, chloride
P-18-0350	11/05/2018	NMR test	(G) aqueous methacrylamido modified polysiloxane
P-11-0557	11/05/2018	Annual import volume (Certificate of Analysis)	(G) 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, telomers with C18-26-alkyl acrylate, 1-dodecanethiol, N-(hydroxymethyl)-2-methyl-2-propenamide, polyfluorooctyl methacrylate and vinylidene chloride, 2,2'-[1,2-diazenediyl]bis(1-methylethylidene)bis[4,5-dihydro-1H-imidazole] hydrochloride (1:2)-initiated
P-12-0242	11/05/2018	Annual import volume (Certificate of Analysis)	(G) 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, telomers with C18-26-alkyl acrylate, 1-dodecanethiol, N-(hydroxymethyl)-2-methyl-2-propenamide, polyfluorooctyl methacrylate, 2,2'-[1,2-diazenediyl]bis(1-methylethylidene)-bis[4,5-dihydro-1H-imidazole] hydrochloride (1:2)-initiated
P-16-0446	11/07/2018	Acute inhalation irritation (OECD 403)	(G) fatty acids, reaction products with alkylamine, polymers with substituted carbomonocycle, substituted alkylamines, heteromonocycle and substituted alkanoate, lactates (salts)

SN-17-0011	11/08/2018	Reproductive and fertility effects test (OECD 416)	(G) polyfluorohydrocarbon
P-16-0543	11/14/2018	Exposure monitoring report	(G) halogenophosphoric acid metal salt
P-17-0253	11/15/2018	Tier 2 inhalation toxicology test (OECD 412)	(G) oxirane, 2-methyl-, polymer with oxirane, methyl 2-(substituted carbomonocycle isoquinolin-2(3H)-yl) propyl ether
P-19-0019	11/20/2018	Bacterial reverse mutation test (OECD 471)	(G) haloalkane
P-11-0063	11/23/2018	Anaerobic Transformation in Soil (OECD 307)	(G) perfluoroalkyl acrylate copolymer
P-14-0712	11/26/2018	PCCD/F EPA Test Method 8290A	(G) plastics, wastes, pyrolyzed, C5-55 fraction
P-17-0195	11/28/2018	Combined Repeated Dose Toxicity Study (OECD 422), Unscheduled DNA Synthesis (OECD 486)	(G) 1,3-Propanediol, 2-methylene- substituted
P-17-0345	11/28/2018	Bovine Corneal Opacity and Permeability (BCOP) (OECD 437)	(G) Polyurethane, methacrylate blocked,

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: March 7, 2019.

Pamela Myrick,

Director,

Information Management Division,

Office of Pollution Prevention and Toxics.

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